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UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
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Washington, D.C. 20231

Patrick M. Ryan  
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Alcon Laboratories, Inc.  
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Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,116,863

#35

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,116,863, which claims the human drug PATANOL® (olopatadine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 571 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 571 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 29, 1997 (62 Fed. Reg. 29143). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (739) + 325 \\ &= 695 \text{ days}\end{aligned}$$

Since the regulatory review period began January 21, 1994, after the patent issue date (May 26, 1992), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 695 days, would extend the patent from May 26, 2009 (35 U.S.C. § 154) to April 21, 2011, which is beyond the 14-year limit (the approval date is December 18, 1996, thus the 14 year limit is December 18, 2010). The period of extension is thus limited to December 18, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, May 26, 2009, to and including December 18, 2010, or 571 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,116,863  
Granted: May 26, 1992  
Original Expiration Date<sup>1</sup>: May 26, 2009  
Applicant: Etsuo Oshima et al.  
Owner of Record: Kyowa Hakko Kogyo Co., Ltd.  
Title: Dibenz[B,E]Oxepin Derivative and Pharmaceutical Compositions Thereof  
Classification: 514/450  
Product Trade Name: PATANOL® (olopatadine hydrochloride)  
Term Extended: 571 days  
Expiration Date of Extension: December 18, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson

Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: PATANOL®  
FDA Docket No.: 97E-0108